RESPONSE

Claims 3, 7 and 10 are pending. The Examiner has rejected the claims on the grounds of non-statutory obviousness-type double patenting citing Applicant's own prior patents: US 6,713,301 and US 6,811,872.

Rejection for double patenting in view of U.S. Patent No. 6,811,782.

All of the pending claims are rejected for non-statutory obviousness-type double patenting on the ground that the present claims is obvious in view of the claims granted and issued in U.S. Patent No. 6,811,782, issued from Application Serial No. 09/701,623.

The rejection on this basis is traversed. The present application is a divisional application of Application Serial No. 09/701,623. During the examination of the parent application, the prior examiner had issued a restriction requirement on the grounds that the claims presented 60 different groups of patentably distinct inventions. Each of the peptides, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, SEQ ID NO:8, SEQ ID NO:84, are patentably distinct. Each of the above peptides conjugated to another peptide are also patentably distinct. A copy of the Office Action dated March 20, 2002 imposing the restriction requirement is enclosed for your convenience and easy reference (EXHIBIT 1).

The present divisional application was filed as a result of the earlier issued restriction requirement.

Under 35 U.S.C. §121 and under MPEP §804.01, the issuance of a double patenting rejection on a divisional application filed in response to a restriction requirement is prohibited. The parent application or the patent issued therefrom may not be used as a reference against the present divisional application.

Thus, the double patenting rejection in view of US 6,811,782 on this basis should be withdrawn.

Rejection for double patenting in view of U.S. Patent No. 6,713,301

The claims of the present application are also rejected on the grounds for double patenting in view of claims 2-6 of U.S. Patent No. 6,713,301, Application Serial No: 09/701,588.

The determination of whether the claims of an application may be objected to for non-statutory, obviousness double patenting was discussed in Pfizer Inc. v. Ranbaxy Laboratory Ltd., 79 USPQ2d 1071 (D. Del. 2005). Citing the Court of Appeals for the Federal circuit (CAFC), the District Court of Delaware pointed out that

> The non-statutory double patenting analysis involves two steps: (1) the court must construe the claim in the earlier patent and the later patent and determine the differences between the two patents, and (2) the court must determine whether the differences in the subject matter between the two claims render the claims patentably distinct. Eli Lilly & Co. v. Barr Laboratory, Inc., 251 F.3d 955, 968; 58 USPQ2d 1865 (Fed. Cir. 2000).

The Court further pointed out that the CAFC had mandated that :

> In assessing the differences between the claims, the court may not treat the earlier claim as prior art. Rather, specific attention must be given to what is claimed in the earlier patent. General Foods Corp. v. Studiengesellschaft Kohle, 972 F.2d 1272, 1278; 23 USPQ2d. 1839 (Fed. Cir. 1992).

And:

> [I]t is important to bear in mind that comparison can be made only with what invention is *claimed* in the earlier patent, paying careful attention to the rules of claim interpretation to determine what invention a claim *defines* and not looking to the claim for anything that happens to be mentioned in it as though it were a prior art reference. (Italics in original). If the later claim is anticipated by or obvious in light of the earlier claim, then the later claim is not patentably distinct from the earlier claim, and it is invalid for obvious-type double patenting, Barr, 251 F.3d at 968.

The Court further explained citing the CAFC that:

> Non-statutory double patenting is a judicially created doctrine, the purpose of which is to preclude a patent owner "from obtaining an extension of the right to exclude others from practicing his invention through claims in a later patent that are not patentably distinct from claims in a commonly

> owned earlier patent.", *Id.* at 967-968. See In re Lonardo, 119 F.3d 960, 965 [43 USPQ2d 1262] (Fed. Cir. 1997).

Further,

> Unlike the obviousness inquiry under 35 U.S.C. §103, non-statutory double patenting does not require an inquiry into the objective criteria of non-obviousness. Geneva Pharms., v. GlaxoSmithKline PLC, 349 F.3d 1373, 1377-1378 n.1 [68 USPQ2d 1865] (Fed. Cir. 2003).

The Court further pointed out that that the CAFC had described the burden of proof for non-statutory double patenting as "heavy and unshifting" Symbol Techs., Inc. v. Option, Inc., 935 F.2d 1569, 1580 [10 USPQ2d 1241] (Fed. Cir. 1991).

Following the mandate by the CAFC as cited by the District Court of Delaware, it is necessary to analyze the claims of the '301 patent. The claims of the '301 patent are directed to promiscuous Th epitopes. Specifically, claims 2 -6 of the '301 patent are directed to a method of use of the promiscuous Th epitopes to prepare a peptide immunogen, where the promiscuous Th epitopes is conjugated to a target antigenic site, optionally with a spacer and further optionally to an Invasin domain peptide. The target antigenic site is not specified. Claims 2-6 of the '301 are reproduced hereinbelow:

2. A T helper cell epitope according to claim 1 for preparing a peptide immunogen represented by the formula

$(A)_n$-(Target antigenic site)-$(B)_o$-$(Th)_m$-X
or
$(A)_n$-$(Th)_m$-$(B)_o$-(Target antigenic site)-X
or
$(A)_n$-$(B)_o$-$(Th)_m$-$(B)_o$-(Target antigenic site)-X
or
(Target antigenic site)-$(B)_o$-$(Th)_n$-$(A)_n$-X
or
$(Th)_m$-$(B)_o$-(Target antigenic site)-$(A)_n$-X

wherein

A is an amino acid or a general immunostimulatory sequence, where n is more than one, the interval A's may be the same or different;

B is selected from the group consisting of amino acids, -HCH(X)CH_2SCH_2CO-, -NHCH(X)CH_2SCH_2CO(-εN)Lys-, -NHCH(X)CH_2S-succinylimidyl-(-εN)Lys-, and NHCH(X)CH_2S-succinylimidyl;

Th is an artificial helper T cell epitope selected from the group of SEQ ID NOS:6-22, 105, 31-35 and an analog thereof:

"Target antigenic site" is selected from the group consisting of a B-cell epitope, a peptide hapten, and a immunologically reactive analog thereof;

X is an amino acid α-COOH or $CONH_2$,
n is from 1 to about 10,
m is from 1 to about 4,
o is form 0 to about 10.

3. A peptide immunogen according to claim 2 wherein the immunostimulatory sequence is SEQ ID NO:78.

4. A peptide immunogen according to claim 2 wherein B is selected from the group consisting Gly-Gly, (-εN)Lys-, Pro-Pro-Xaa-Pro-Pro, -HCH(X)CH_2SCH_2CO-, -NHCH(X)CH_2SCH_2CO(-εN)Lys-, -NHCH(X)CH_2S-succinylimidyl(-εN)Lys-, and NHCH(X)CH_2S-succinylimidyl;

5. A peptide immunogen according to claim 2 wherein B is Gly-Gly.

6. A peptide immunogen according to claim 2 wherein B is (-εN)Lys.

Thus, claims 2-6 are directed to a method of using the Th epitopes to prepare a peptide immunogen. The "target antigenic site" is defined as a B-cell epitope, a peptide hapten, and a immunologically reactive analog thereof. There is no recital of an IgE-CH3 epitope. There is no recital of a peptide immunogen for the treatment of allergy.

In contrast, the claims of the present application is specifically directed to peptide immunogens for the treatment of allergy, where a B-cell epitope of the present claimed invention is derived from IgE-CH3 and is specific. There is no disclosure, description or suggestion of the IgE-CH3 B-cell epitopes of the present application in the '301 patent. The B-cell epitope is a fragment of IgE-CH3. It is not anticipated by or obvious in view of the "target antigenic site" of claims 2-6 of the '301 patent. There is not extension of the rights granted under the '301 patent. In order to be covered by the claims of the present application, it is necessary to have a peptide immunogen that comprises the IgE-CH3 epitope of claims 3, 7 and 10 of the present application.

The claimed subject matter of the present application is novel over the subject matter of claims 2-6 the '301 patent. Moreover, the claimed subject matter of the present

application, not being described, disclosed or taught by the '301 patent, cannot be rejected on the basis of non-statutory obviousness-type double patenting over claims 2-6 of the '301 patent.

The Examiner pointed to claims 2-6 of the '301 patent as reading on claims 3, 7, 10 of the present application. The Examiner stated that the target antigenic site of the '301 patent reads on the IgE-CH3 epitope of the present application. However, this is not the mandate. The mandate is to analyze claims 3, 7 and 10 of the present application and determine whether the subject matter of these claims is anticipated or obvious in view of claims 2-6 of the '301 patent, keeping in mind that the '301 patent is not to be treated as a prior reference.

In fact, a review of the analysis by the District Court of Delaware in the Pfizer v. Ranbaxy case cited above is instructive. The Court analyzed claims 12 and 14 of the earlier patent and determined that claim 12 is directed to a method of preparing certain lactone compounds and the opening of the lactone ring to form hydroxyl acids and pharmaceutically acceptable salts thereof. And, claim 14 is directed to the preparation of a single compound, atorvastatin lactone. The Court also construed the objected to claim 6 of the patent at issue as being directed to atorvastatin calcium.

Having construed claims 12 and 14 of the earlier patent and objected claim 6 of the patent at issue, the Court found that the process of claim 12 and the single compound of claim 14 are not contemplated by claim 6 and held that claim 6 is patentably distinct from claims 12 or 14 of the earlier patent.

Following this analysis, it is clear that a method of using promiscuous Th epitopes as defined by claims 2-6 of the '301 patent are not contemplated by claims 3, 7 and 10 which are directed to IgE-CH3 epitope linked to a promiscuous Th epitope, where claims 3, 7, and 10 define a patentably distinct invention.

Moreover, based on the restriction requirement that had issued in the parent application and other applications directed to peptides with specific sequences, it is clear that every combination of a specified B-cell epitope with a different specified Th epitopes is regarded as patentably distinct. Thus, the present rejection for double patenting is improper when the invention claimed as a whole has long been regarded by the Office as patentably distinct for purposes of a restriction requirement. The claims of the present application are a combination of specific B-cell epitopes of IgE-CH3 with specific promiscuous Th epitopes.

Since the claimed subject matter of the present application is different and distinct from the claims of the '301 patent, non-statutory obviousness-type double patenting in view of claims 2-6 of the '301 patent is improper and should be withdrawn.

CONCLUSION

Based on the foregoing remarks, Applicants respectfully request reconsideration and entry of the listing of claims presented herein, and furthermore, withdrawal of the rejection of claims and allowance of this application. Favorable action by the Examiner is earnestly solicited.

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. **13-4500**, Order No. 1151-4153US2.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. **13-4500**, Order No. 1151-4153US2.

Respectfully submitted,
MORGAN & FINNEGAN, L.L.P.

Dated: August 22, 2008 By: _____
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EXHIBIT 1

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,623	12/01/2000	Chang Yi Wang	1151-4153US1	8939

7590 03/20/2002

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EXAMINER	
JAMROZ, MARGARET E	

ART UNIT	PAPER NUMBER
1644	13

DATE MAILED: 03/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No.	Applicant(s)	
09/701,623	WANG ET AL.	
Examiner	**Art Unit**	
Margaret E Jamroz	1644	

Offic Action Summary

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-28* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *restriction election facsimile* .

DETAILED ACTION

1. The location of your application in the PTO has changed. To aid in correlating papers for this application, all further correspondence regarding this application should be directed to Megan Jamroz in Art Unit 1644, Technology Center 1600.

Restriction Requirement

2. Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

In view of the delays in the mail at the present time, the office strongly encourages faxing responses.

Restriction

3. Restriction is required under 35 U.S.C. 121 and 372.
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted:

1. Claims 1-2 and 19-20, drawn to SEQ ID NO: 5, an IgE-CH3 domain antigen peptide between about 25 and 29 amino acids in length, homologous sequences, crossreactive, immunologically functional analogs thereof.

2. Claims 1-2 and 19-20, drawn to SEQ ID NO: 6, an IgE-CH3 domain antigen peptide between about 25 and 29 amino acids in length, homologous sequences, crossreactive, and immunologically functional analogs thereof.

3. Claims 1-2 and 19-20, drawn to SEQ ID NO: 7, an IgE-CH3 domain antigen peptide between about 25 and 29 amino acids in length, homologous sequences, crossreactive, and immunologically functional analogs thereof.

4. Claims 1-2 and 19-20, drawn to SEQ ID NO: 8, an IgE-CH3 domain antigen peptide between about 25 and 29 amino acids in length, homologous sequences, crossreactive, and immunologically functional analogs thereof.

5. Claims 1-2 and 19-20, drawn to SEQ ID NO: 84, an IgE-CH3 domain antigen peptide between about 25 and 29 amino acids in length, homologous sequences, crossreactive, and immunologically functional analogs thereof.

6. Claims 3-13, 15-18, and 22-25, drawn to a synthetic peptide conjugate comprising SEQ ID NO: 5.

7. Claims 3-13, 15-18, and 22-25, drawn to a synthetic peptide conjugate comprising SEQ ID NO: 6.

8. Claims 3-13, 15-18, and 22-25, drawn to a synthetic peptide conjugate comprising SEQ ID NO: 7.

9. Claims 3-13, 15-18, and 22-25, drawn to a synthetic peptide conjugate comprising SEQ ID NO: 8.

10. Claims 3-13, 15-18, and 22-25, drawn to a synthetic peptide conjugate comprising SEQ ID NO: 84.

11. Claims 14 and 21-25, drawn to a peptide comprising an amino acid sequence of SEQ ID NO: 14, a branched polymer thereof, or a cross-lined polymer thereof, and a pharmaceutical composition thereof.

12. Claims 14 and 21-25, drawn to a peptide comprising an amino acid sequence of SEQ ID NO: 15, a branched polymer thereof, or a cross-lined polymer thereof, and a pharmaceutical composition thereof.

13. Claims 14 and 22-25, drawn to a peptide comprising an amino acid sequence of SEQ ID NO: 17, a branched polymer thereof, or a cross-lined polymer thereof, and a pharmaceutical composition thereof.

14. Claims 14 and 22-25, drawn to a peptide comprising an amino acid sequence of SEQ ID NO: 18, or a branched polymer, a cross-lined polymer, and a pharmaceutical composition thereof.

15. Claims 14 and 22-25, drawn to a peptide comprising an amino acid sequence of SEQ ID NO: 19, a branched polymer thereof, or a cross-lined polymer thereof, and a pharmaceutical composition thereof.

16. Claims 14 and 22-25, drawn to a peptide comprising an amino acid sequence of SEQ ID NO: 20, a branched polymer thereof, or a cross-lined polymer thereof, and a pharmaceutical composition thereof.

17. Claims 14 and 22-25, drawn to a peptide comprising an amino acid sequence of SEQ ID NO: 21, a branched polymer thereof, or a cross-lined polymer thereof, and a pharmaceutical composition thereof.

18. Claims 14 and 22-25, drawn to a peptide comprising an amino acid sequence of SEQ ID NO: 22, a branched polymer thereof, or a cross-lined polymer thereof, and a pharmaceutical composition thereof.

19. Claims 14 and 22-25, drawn to a peptide comprising an amino acid sequence of SEQ ID NO: 23, a branched polymer thereof, or a cross-lined polymer thereof, and a pharmaceutical composition thereof.

20. Claims 14 and 22-25, drawn to a peptide comprising an amino acid sequence of SEQ ID NO: 24, a branched polymer thereof, or a cross-lined polymer thereof, and a pharmaceutical composition thereof.

21. Claims 14 and 22-25, drawn to a peptide comprising an amino acid sequence of SEQ ID NO: 25, a branched polymer thereof, or a cross-lined polymer thereof, and a pharmaceutical composition thereof.

22. Claims 14 and 21-25, drawn to a peptide comprising an amino acid sequence of SEQ ID NO: 26, a branched polymer thereof, or a cross-lined polymer thereof, and a pharmaceutical composition thereof.

23. Claims 14 and 22-25, drawn to a peptide comprising an amino acid sequence of SEQ ID NO: 27, a branched polymer thereof, or a cross-lined polymer thereof, and a pharmaceutical composition thereof.

24. Claims 14 and 22-25, drawn to a peptide comprising an amino acid sequence of SEQ ID NO: 85, a branched polymer thereof, or a cross-lined polymer thereof, and a pharmaceutical composition thereof.

25. Claims 14 and 22-25, drawn to a peptide comprising an amino acid sequence of SEQ ID NO: 87, a branched polymer thereof, or a cross-lined polymer thereof, and a pharmaceutical composition thereof.

26. Claims 14 and 22-25, drawn to a peptide comprising an amino acid sequence of SEQ ID NO: 88, a branched polymer thereof, or a cross-lined polymer thereof, and a pharmaceutical composition thereof.

27. Claims 14 and 21-25, drawn to a peptide comprising an amino acid sequence of SEQ ID NO: 90, a branched polymer thereof, or a cross-lined polymer thereof, and a pharmaceutical composition thereof.

28. Claims 14 and 22-25, drawn to a peptide comprising an amino acid sequence of SEQ ID NO: 91, a branched polymer thereof, or a cross-lined polymer thereof, and a pharmaceutical composition thereof.

29. Claims 26-27, drawn to a method for inducing anti-IgE antibody production in a mammal comprising administering a pharmaceutical composition of a peptide conjugate comprising a Th epitope and SEQ ID NO: 5, a branched polymer thereof, or a cross-lined polymer thereof.

30. Claims 26-27, drawn to a method for inducing anti-IgE antibody production in a mammal comprising administering a pharmaceutical composition of a peptide conjugate comprising a Th epitope and SEQ ID NO: 6, a branched polymer thereof, or a cross-lined polymer thereof.

31. Claims 26-27, drawn to a method for inducing anti-IgE antibody production in a mammal comprising administering a pharmaceutical composition of a peptide conjugate comprising a Th epitope and SEQ ID NO: 7, a branched polymer thereof, or a cross-lined polymer thereof.

32. Claims 26-27, drawn to a method for inducing anti-IgE antibody production in a mammal comprising administering a pharmaceutical composition of a peptide conjugate comprising a Th epitope and SEQ ID NO: 8, a branched polymer thereof, or a cross-lined polymer thereof.

33. Claims 26-27, drawn to a method for inducing anti-IgE antibody production in a mammal comprising administering a pharmaceutical composition of a peptide conjugate comprising a Th epitope and SEQ ID NO: 84, a branched polymer thereof, or a cross-lined polymer thereof.

34. Claims 26-27, drawn to a method for inducing anti-IgE antibody production in a mammal comprising administering a pharmaceutical composition of a peptide conjugate comprising SEQ ID NO: 14, a branched polymer thereof, or a cross-lined polymer thereof.

35. Claims 26-27, drawn to a method for inducing anti-IgE antibody production in a mammal comprising administering a pharmaceutical composition of a peptide conjugate comprising SEQ ID NO: 15, a branched polymer thereof, or a cross-lined polymer thereof.

36. Claims 26-27, drawn to a method for inducing anti-IgE antibody production in a mammal comprising administering a pharmaceutical composition of a peptide conjugate comprising SEQ ID NO: 17, a branched polymer thereof, or a cross-lined polymer thereof.

37. Claims 26-27, drawn to a method for inducing anti-IgE antibody production in a mammal comprising administering a pharmaceutical composition of a peptide conjugate comprising SEQ ID NO: 18, a branched polymer thereof, or a cross-lined polymer thereof.

38. Claims 26-27, drawn to a method for inducing anti-IgE antibody production in a mammal comprising administering a pharmaceutical composition of a peptide conjugate comprising SEQ ID NO: 19, a branched polymer thereof, or a cross-lined polymer thereof.

39. Claims 26-27, drawn to a method for inducing anti-IgE antibody production in a mammal comprising administering a pharmaceutical composition of a peptide conjugate comprising SEQ ID NO: 20, a branched polymer thereof, or a cross-lined polymer thereof.

40. Claims 26-27, drawn to a method for inducing anti-IgE antibody production in a mammal comprising administering a pharmaceutical composition of a peptide conjugate comprising SEQ ID NO: 21, a branched polymer thereof, or a cross-lined polymer thereof.

41. Claims 26-27, drawn to a method for inducing anti-IgE antibody production in a mammal comprising administering a pharmaceutical composition of a peptide conjugate comprising SEQ ID NO: 22, a branched polymer thereof, or a cross-lined polymer thereof.

42. Claims 26-27, drawn to a method for inducing anti-IgE antibody production in a mammal comprising administering a pharmaceutical composition of a peptide conjugate comprising SEQ ID NO: 23, a branched polymer thereof, or a cross-lined polymer thereof.

43. Claims 26-27, drawn to a method for inducing anti-IgE antibody production in a mammal comprising administering a pharmaceutical composition of a peptide conjugate comprising SEQ ID NO: 24, a branched polymer thereof, or a cross-lined polymer thereof.

44. Claims 26-27, drawn to a method for inducing anti-IgE antibody production in a mammal comprising administering a pharmaceutical composition of a peptide conjugate comprising SEQ ID NO: 25, a branched polymer thereof, or a cross-lined polymer thereof.

45. Claims 26-27, drawn to a method for inducing anti-IgE antibody production in a mammal comprising administering a pharmaceutical composition of a peptide conjugate comprising SEQ ID NO: 26, a branched polymer thereof, or a cross-lined polymer thereof.

46. Claims 26-27, drawn to a method for inducing anti-IgE antibody production in a mammal comprising administering a pharmaceutical composition of a peptide conjugate comprising SEQ ID NO: 27, a branched polymer thereof, or a cross-lined polymer thereof.

47. Claims 26-27, drawn to a method for inducing anti-IgE antibody production in a mammal comprising administering a pharmaceutical composition of a peptide conjugate comprising SEQ ID NO: 85, a branched polymer thereof, or a cross-lined polymer thereof.

48. Claims 26-27, drawn to a method for inducing anti-IgE antibody production in a mammal comprising administering a pharmaceutical composition of a peptide conjugate comprising SEQ ID NO: 87, a branched polymer thereof, or a cross-lined polymer thereof.

49. Claims 26-27, drawn to a method for inducing anti-IgE antibody production in a mammal comprising administering a pharmaceutical composition of a peptide conjugate comprising SEQ ID NO: 88, a branched polymer thereof, or a cross-lined polymer thereof.

50. Claims 26-27, drawn to a method for inducing anti-IgE antibody production in a mammal comprising administering a pharmaceutical composition of a peptide conjugate comprising SEQ ID NO: 89, a branched polymer thereof, or a cross-lined polymer thereof.

51. Claim 28, drawn to a nucleic acid comprising a sequence which encodes the peptide of SEQ ID NO: 5.

52. Claim 28, drawn to a nucleic acid comprising a sequence which encodes the peptide of SEQ ID NO: 6.

53. Claim 28, drawn to a nucleic acid comprising a sequence which encodes the peptide of SEQ ID NO: 7.

54. Claim 28, drawn to a nucleic acid comprising a sequence which encodes the peptide of SEQ ID NO: 8.

55. Claim 28, drawn to a nucleic acid comprising a sequence which encodes the peptide of SEQ ID NO: 84.

56. Claim 28, drawn to a nucleic acid comprising a sequence which encodes a peptide conjugate comprising SEQ ID NO: 5.

57. Claim 28, drawn to a nucleic acid comprising a sequence which encodes a peptide conjugate comprising SEQ ID NO: 6.

58. Claim 28, drawn to a nucleic acid comprising a sequence which encodes a peptide conjugate comprising SEQ ID NO: 7.

59. Claim 28, drawn to a nucleic acid comprising a sequence which encodes a peptide conjugate comprising SEQ ID NO: 8.

60. Claim 28, drawn to a nucleic acid comprising a sequence which encodes a peptide conjugate comprising SEQ ID NO: 84.

4. The inventions listed as Groups 1-60 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Pursuant to 37 CFR 1.475(d), the ISA/US considers that where multiple products and processes are claimed, the main invention shall consist of the first invention of the category first mentioned in the claims and the first recited invention of each of the other categories related thereto. Accordingly, the main invention (Group I) comprises the first recited product, (SEQ ID NO: 5, an IgE-CH3 domain antigen peptide between about 25 and 29 amino acids in length, homologous sequences, crossreactive, immunologically functional analogs thereof). Further pursuant to 37 CFR 1.475(d), the ISA/US considers that any feature which the subsequently recited products and methods share with the main invention does not constitute a special technical feature within the meaning of PCT Rule 13.2 and that each of such products and methods accordingly defines a separate invention.

Since Applicant's Inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

Species Election

5. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

(1) If applicant elects one of Groups 6-10, applicant is further required to elect a specific peptide conjugate wherein A is a specific amino acid (e.g. proline) or a specific general immunostimulatory sequence and wherein n is a specific number (e.g. 0); wherein B is chosen from the specific amino acids (such as one of those recited in claim 6) and wherein 0 is a specific number (e.g. 1); wherein the IgE-CH3 domain antigen is a specific sequence (e.g. SEQ ID NO: 5); wherein Tm is a specific sequence of amino acids constituting a helper T cell epitope (e.g. SEQ ID NO: 9) and wherein m is a specific number (e.g. 1); and wherein X is a specific amino acid; or a specific nucleic acid sequence which encode them, respectively.

The claims are deemed to correspond to the species listed above: claims 4, 5, and 6.

(2) If applicant elects one of Groups 11-28, applicant is further required to elect a specific branched polymer comprising a specific lysine core (e.g. lysine) covalently attached to a specific number of peptide conjugates.

The claims are deemed to correspond to the species listed above: claims 4, 5, 6, and 22.

(3) If applicant elects one of Groups 29-50, applicant, applicant is further required to elect a specific method for inducing anti-IgE production comprising administering a specific peptide conjugate wherein A is a specific amino acid (e.g. proline) or a specific general immunostimulatory sequence and wherein n is a specific number (e.g. 0); wherein B is chosen from the specific amino acids (such as one of those recited in claim 6) and wherein 0 is a specific number (e.g. 1); wherein the IgE-CH3 domain antigen is a specific sequence (e.g. SEQ ID NO: 5); wherein Tm is a specific sequence of amino acids constituting a helper T cell epitope (e.g. SEQ ID NO: 9) and wherein m is a specific number (e.g. 1); and wherein X is a specific amino acid; or administering a specific branched polymer comprising a specific lysine core (e.g. lysine) covalently attached to a specific number of peptide conjugates (e.g. two).

The claims are deemed to correspond to the species listed above: claims 4, 5, 6, and 26.

(4) If applicant elects one of Groups 56-60, applicant is required to elect a specific nucleic acid comprising a sequence which encodes a specific peptide conjugate wherein A is a specific amino acid (e.g. proline) or a specific general immunostimulatory sequence and wherein n is a specific number (e.g. 0); wherein B is chosen from the specific amino acids (such as one of those recited in claim 6) and wherein 0 is a specific number (e.g. 1); wherein the IgE-CH3 domain antigen is a specific sequence (e.g. SEQ ID NO: 5); wherein Tm is a specific sequence of amino acids constituting a helper T cell epitope (e.g. SEQ ID NO: 9) and wherein m is a specific number (e.g. 1); and wherein X is a specific amino acid; or administering a specific branched polymer comprising a specific lysine core (e.g. lysine) covalently attached to a specific number of peptide conjugates (e.g. two).

The claims are deemed to correspond to the species listed above: claims 1, 4, 5, 6, and 28.

6. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

7. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Megan Jamroz, whose telephone number is (703) 308-8365. The examiner can normally be reached Monday to Friday, 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Margaret (Megan) Jamroz, Ph.D.
Patent Examiner
Technology Center 1600
March 19, 2002

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SUPERVISORY PATENT EXAMINER
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